

### REMARKS/ARGUMENTS

The claims are 3-11. Claims 11 and dependent claim 3 and 5-8 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Isaacson U.S. Patent No. 4,479,495* in view of *DE 3 300 11 to Thomas*. The remaining claims are rejected under 35 U.S.C. §103(a) as being unpatentable over *Isaacson* and *DE 3 300 11 to Thomas* in view of either *Sweitzer U.S. Patent No. 4,299,214* (claim 4) or *Mason et al. U.S. Patent No. 4,938,777* (claims 9-10).

Essentially, the Examiner's position was that *Isaacson* shows the orthosis cuff recited in the claims, except for the cuff being made of stiff plastic which can be shaped to conform to a specific foot and configured with cushion, that *DE 3 300 11 to Thomas* teaches this feature, and that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use stiff material for the functional component 10 of *Isaacson* in order to provide firmer support around the upper ankle joint area of a user. *Sweitzer* is cited with respect to claim 4 as teaching a cuff made of stiff plastic material wherein the closing elements are belts and

buckles. *Mason et al.* is cited with respect to claims 9 and 10 as teaching an ankle orthosis made of polycarbonate or stainless steel.

This rejection is respectfully traversed.

As set forth in claim 11, Applicants' invention provides an orthosis cuff for the treatment or therapy of Ledderhose's disease or hypermobile foot joints that includes a functional component made of stiff material and a pad having a convex surface arranged on an inside portion of the functional component. The functional component is adapted to the outer contour of a wearer's lower leg and surrounds the lower leg near the upper ankle joint so that when the cuff is worn, the mobility of the wearer's upper ankle joint and the Achilles tendon is not restricted. The pad is arranged so that when the cuff is worn the convex surface rests anteriolaterally on the wearer's leg against the fibula and tibia in the region of the wearer's tibiofibular syndesmosis so that the tibiofibular syndesmosis is stabilized.

With Applicants' orthosis cuff, the cuff in general and the pad in particular is fitted without creating noticeable pressure when the foot is not in movement. When the foot is activating or in movement, Applicants' cuff restricts the small movement of the fibula to the tibia and holds it fixed in the area of the syndesmosis which holds the tibia and fibula together so that the sinews of the foot are supported and stabilized, thus assisting the sinew/movement to function properly because the pad applies pressure to the fibula when the foot is in movement and inhibits the play of the fibula. By so doing, the torque movement of the sinews in the metatarsal bones are improved, which in turn gives an improved stability of the foot movement.

Attached hereto for illustration purposes are drawings labeled No. 1 and No. 2, illustrating the operation of Applicants' cuff. As can be seen in the drawings, the cuff supports the foot sole and Articulatio talocruralis and Articulatio talocalcaneonavicularis/Articulatio subtalaris. As a result, the cuff restricts the occurrence of hypermobile foot joints and alleviates the pain resulting from Ledderhose's disease.

*Isaacson* fails to disclose or suggest an orthosis cuff that is suitable for the treatment or therapy of Ledderhose's disease or hypermobile foot joints or an orthosis cuff having a pad with a convex surface able to rest anterioplaterally on a wearer's leg against the fibula and tibia in the region of the wearer's tibiofibular syndesmosis so that the tibiofibular syndesmosis can be stabilized. *Isaacson* discloses an acupuncture device for applying pressure to specific points on a human body. The device includes a stimulator (14) which is attached to a flexible cinching strap or band (10) of a length sufficient to extend circumferentially around a body part. The stimulator has a convex curved side (26) but in contrast to Applicants' orthosis cuff, the convex curved side is attached to the flexible strap, rather than to the part that is in contact with the wearer's leg.

Opposite the curved side (26) and extending therefrom, *Isaacson* uses a elongated protuberance (20), which extends and terminates in a blunt or pointed surface end (22) that contacts and applies pressure to a selected point on the user's body. Although FIG. 3D of *Isaacson* shows a terminus of the protrusion with a rounded or hemispherical contact point, it is clear from *Isaacson* that the purpose of this contact point is to provide

constant force in a perpendicular direction to stimulate an acupressure point and therefore could not serve to rest anteriolaterally on the wearer's leg against the fibula and tibia in the region of the wearer's tibiofibular syndesmosis or to stabilize the tibiofibular syndesmosis as recited in Applicants' claims. As shown in FIG. 2 of *Isaacson* for example, the contact point is too narrow to rest against these structures or to provide the necessary stabilization.

Moreover, not only does *Isaacson* have a different structure from Applicants' orthosis cuff as recited in claim 11 where the convex surface of the pad must be broad enough to rest anterolaterally against the fibula and tibia, the effect of *Isaacson's* acupuncture point pressure pad is completely different as *Isaacson's* pad is permanently active even when the foot is not moving as compared with Applicants' pad, which gives side support when the foot is in motion and rests when the foot is not in motion.

The defects and deficiencies of the primary reference to *Isaacson* are nowhere remedied by any of the secondary references

DE 33 00 111 to Thomas, Sweitzer or Mason et al. As previously explained in Applicants' May 26, 2005 Preliminary Amendment DE 33 00 111 to Thomas discloses a brace, which in the applied condition grips around a large part of the back of the foot as well as of the adjoining upper ankle joint, and for this reason alone is entirely noncompatible with Applicants' orthosis cuff as recited in claim 11, in which the functional component surrounds the lower leg near the upper ankle joint so that when the cuff is worn the mobility of the wearer's upper ankle joint and the Achilles tendon is not restricted. Although DE 33 00 111 to Thomas says that his clip-like or cuff-like part may be made from a plastic that can be shaped to conform to a specific foot, there is no disclosure or suggestion of Applicants' orthosis cuff having a pad with a convex surface that rests anterolaterally on the wearer's leg against the fibula and tibia in the region of the wearer's tibiofibular syndesmosis so that the tibiofibular syndesmosis is stabilized.

Sweitzer discloses a rigid cuff for the relief of tennis elbow. If worn on the leg, this system would fix the complete ankle including the Achilles tendon. In contrast, Applicants' orthosis cuff does not cover the complete foot and moving ankle

parts but only support the sinews of the foot during movement. Like *DE 33 00 111 to Thomas*, there is no disclosure or suggestion of Applicants' orthosis cuff in which a pad having a convex surface rests anterolaterally on the wearer's leg against the fibula and tibia in the region of the wearer's tibiofibular syndesmosis so that the tibiofibular syndesmosis is stabilized.

Similarly, as previously explained in Applicants' May 26, 2005 Preliminary Amendment, *Mason et al.* orthosis cuff attempts to prevent the eversion and inversion of the foot and therefore restricts the mobility of the wearer's upper ankle joint. See column 2, line 62 of *Mason et al.* Unlike Applicants' orthosis cuff, moreover, *Mason et al.*'s ankle orthosis teaches that it is necessary to have a rib 10 composed of a single vertical riser 12 and a lower cup shoe or section to achieve its objectives. See also FIGS. 1, 3-6 and 9. These structures restrict movement of the wearer's ankle and leg. For example, a person wearing *Mason et al.*'s cuff cannot stand on the balls of his feet because of the restriction at the back of the leg, ankle and foot. In contrast, Applicants' orthosis cuff has no such rib or other structure restricting movement. In Applicants' cuff, mobility of the ankle is entirely

unrestricted. Moreover, Applicants' cuff contains a pad having a convex surface resting anterolaterally on the wearer's leg against the fibula and tibia in the region of the wearer's tibiofibular syndesmosis, which stabilizes the tibiofibular syndesmosis, which is nowhere disclosed or suggested by *Mason et al.*

Therefore, none of the references whether alone or in combination discloses or suggests Applicants' orthosis cuff for the treatment or therapy of Ledderhose's disease or hypermobile foot joints. In particular, none of the references disclose a pad having a convex surface arranged on the inside portion of a functional component so that when the cuff is worn, the convex surface rests anterolaterally on the wearer's leg against the fibula and tibia in the region of the wearer's tibiofibular syndesmosis so that the tibiofibular syndesmosis is stabilized. Accordingly, it is respectfully submitted that claim 11 and claims 3-10 dependent thereon are patentable over the cited references.

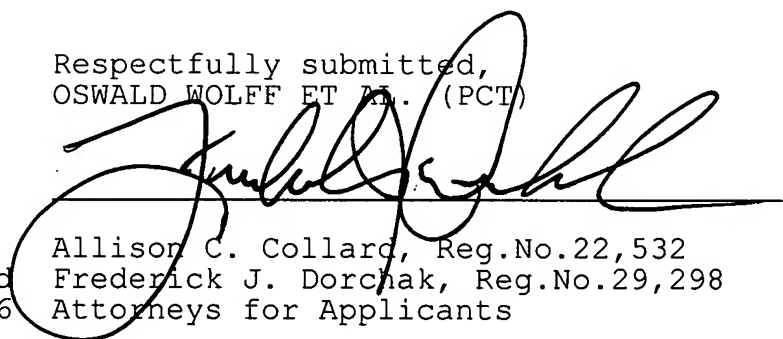
Applicants also respectfully request that the Examiner make of record the reference *DE 182 52 328*, which was listed on Applicants' PTO-Form 1449 submitted May 26, 2005. Although the Examiner initially indicated that she did not have a copy of this reference, as discussed with the Examiner in a telephone conference on August 15, 2005, the reference along with an



English translation was submitted by Applicants and appears in the electronic record for this Application in the Patent Office records under "NPL Documents Prior Art" mail room date May 26, 2005. In the telephone conference on August 15, 2005, the Examiner indicated that she would make the reference of record, and for this purpose Applicants enclose herewith another 1449 Form listing this reference for the Examiner's convenience.

In view of the foregoing, it is respectfully requested that the claims be allowed and that this case be passed to issue.

Respectfully submitted,  
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PTO Form 1449

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on November 7, 2005.

  
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